

Appl. No. 09/488,728  
RCE filed October 25, 2004

### 3. Remarks

Applicant respectfully requests reconsideration and allowance of the claims. Following the amendments, claims 13, 17, and 19-28 are pending, with claims 13, 17, 19-21, and 24-26 being in independent form.

Claims 13 and 17 have been amended to specify that the soluble IL-17R protein is selected from the group consisting of: (a) a protein comprising amino acids 28 through 320 of SEQ ID NO:4; (b) a protein comprising an amino acid sequence that is at least 80% identical to the amino acid sequence of (a) that binds IL-17; and (c) a fragment of (a) that binds IL-17.

Support for a protein comprising amino acids 28 through 320 of SEQ ID NO:4 may be found at page 4 lines 17-27. At lines 19-20, the specification teaches that the signal sequence ends at amino acid 27 and the extracellular domain begins at amino acid 28. Thus, amino acids 28-320 define the extracellular domain without the signal sequence. As stated at lines 25-26, "a soluble IL-17R comprises the signal peptide and the extracellular domain.....or a fragment thereof." In addition, the Examples describe the use of an IL-17R-Fc fusion protein in which the signal sequence had been cleaved from the mature fusion protein (as a natural process of its expression and secretion).

Support for 80% variants may be found at page 10, line 11.

Applicant has added new claims 19-28. Claims 19-21 and 24-26 are independent claims for the individual members of the Markush groups of claims 13 and 17, respectively. Claims 22 and 27 are dependent claims specifying that the soluble IL-17R protein further comprises an Fc domain. Support for Fc fusion proteins may be found, for example, at page 5, lines 7-11 and Examples 1 and 2. Claims 23 and 28 are dependent claims specifying that the soluble IL-17R protein further comprises an oligomerizing domain. Support for oligomerizing domains may be found, for example, at page 5, line 37 to page 7, line 25.

No new matter has been added.

#### **35 U.S.C. §112, first paragraph**

Claims 13-18 stand rejected under 35 U.S.C. §112, first paragraph as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and use the claimed invention.

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The Examiner states that neither the prior art nor the present disclosure has demonstrated an association of IL-17 to ulcerative colitis and Crohn's disease, and therefore, in the absence of predictability of involvement of IL-17 in said diseases, it is unpredictable that the treatment of the diseases with soluble IL-17R would be predictable.

In response, Applicant incorporates his prior arguments of record into this response and includes the following publication: S Fujino, et al., Increased expression of Interleukin 17 in inflammatory bowel disease, *Gut* 2003;52:65-70. In the opening sentence the authors state that IBD includes ulcerative colitis and Crohn's disease. The last sentence of the third paragraph of page 65, the authors state that "[o]ur results provide evidence that IL-17 is over expressed in the inflamed mucosa of IBD and may therefore contribute to the pathophysiology of IBD."

Having satisfied the Examiner's request that Applicant show a direct link between IL-17 and ulcerative colitis and Crohn's disease, Applicant respectfully requests that the rejection under 35 U.S.C. §112, first paragraph be properly withdrawn.

The Examiner is invited to contact the undersigned to discuss any remaining issues in order to facilitate early allowance of the application.

Respectfully submitted,

  
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#### CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below.

Signed:   
Nanci M. Kerison

Date: Oct 25, 2004